

No. 14-15180

In the United States Court of Appeals  
For The Ninth Circuit

---

THERMOLIFE INTERNATIONAL, LLC,  
an Arizona limited liability company,  
Plaintiff, Counter-Defendant and Appellant,

v.

GASPARI NUTRITION, INCORPORATED,  
a New Jersey corporation,  
Defendant, Counter-Claimant and Appellee.

---

**APPELLANT'S OPENING BRIEF  
(PUBLIC VERSION [CONTAINING REDACTIONS OF  
CONFIDENTIAL PASSAGES])**

---

Appeal From A Judgment Following An Order Entering Judgment  
Against Plaintiff on Its First Amended Complaint and  
From an Order Denying a Rule 59(e) Motion to Alter or Amend the Judgment and  
From the Court's Amended Judgment on Taxation of Costs  
United States District Court, District of Arizona, Case No. 2:11-cv-01056-NVW  
Honorable Neil V. Wake, United States District Judge

---

Raymond A. Cardozo (CA SBN 173263)  
rcardozo@reedsmith.com  
Reed Smith LLP  
101 Second Street, Suite 1800  
San Francisco, CA 94105-3659  
Telephone: 415 543-8700; Fax: 415 391-8269

Michael H. Sampson (PA SBN 92574)  
msampson@reedsmith.com  
Reed Smith LLP  
225 Fifth Avenue  
Pittsburgh, PA 15222  
Telephone: 412 288-3131; Fax: 412 288-3063

Geoffrey S. Kercsmar (AZ SBN 020528)  
gsk@kflawaz.com  
Gregory B. Collins (AZ SBN 023158)  
gbc@kflawaz.com  
C. Molly Eskay (AZ SBN 028212)  
cme@kflawaz.com  
Kercsmar & Feltus PLLC  
7150 East Camelback Road, Suite 285  
Scottsdale, AZ 85251  
Telephone: 480 421-1001  
Fax: 480 421-1002

*Attorneys for Plaintiff, Counter-Defendant and Appellant  
ThermoLife International, LLC*

**CORPORATE DISCLOSURE STATEMENT**

**(Fed. R. App. P. 26.1)**

ThermoLife International, LLC is a nongovernmental corporate party that has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

DATED: July 10, 2014

KERCSMAR & FELTUS PLLC

REED SMITH LLP

By /s/ Raymond A. Cardozo  
Raymond A. Cardozo

Attorneys for Plaintiff, Counter-Defendant  
and Appellant ThermoLife  
International, LLC

## **TABLE OF CONTENTS**

	<u>Page</u>
CORPORATE DISCLOSURE STATEMENT .....	i
TABLE OF AUTHORITIES .....	vi
INTRODUCTION .....	1
JURISDICTIONAL STATEMENT .....	5
STATEMENT OF THE ISSUES.....	5
STATEMENT OF THE CASE.....	7
I STATEMENT OF THE FACTS.....	7
A. 2005–2010: ThermoLife Sells Safe And Natural Supplements; GNI, Without The FDA’s Approval, Falsely Touts Its Steroidal Products As “Dietary Supplements” That Are “Natural,” “Safe,” “Supported by Rock-Solid Safety Data” And “Legal” .....	7
B. 2010: The FDA Finds GNI’s Products Contain Illegal And Unsafe Synthetic Steroids, Triggering Their Recall From The Market.....	8
C. 2011–Present: ThermoLife Sues To Obtain A Remedy For GNI’s False Advertising And Presents Evidence That GNI’s Advertisements Were False, Were Material And Caused Injury.....	10
1. GNI’s Advertising Was False .....	11
2. GNI’s Advertising Statements Were Material.....	13
3. GNI’s False Advertising Harmed ThermoLife.....	15
II PROCEEDINGS AND DISPOSITION BELOW .....	16
A. After Hearing The Summary Judgment, <i>Daubert</i> And Sanctions Motions, The District Court Excludes Every Expert, Grants Summary Judgment, And Declines To Sanction GNI .....	16

1.	The Court Finds Preemption And Lack Of Falsity For Counts I-II & V (Advertising GNI Products as Legal or DSHEA-Compliant).....	17
2.	After Excluding The Opinions Of A Safety Expert, The Court Also Finds Preemption Of Counts IV & VI (GNI Advertising Products As “Safe” and Supported By “Rock-Solid Safety Data”).....	18
3.	On Count III, The Court Finds GNI’s False Advertising Of Its Products As “Natural” And “Naturally Occurring” To Be A Mere Opinion .....	19
4.	The Court Rules No Reasonable Trier Of Fact Could Find Materiality.....	19
5.	The Court Finds No Triable Issue On Injury .....	20
6.	The Court Erroneously Rules ThermoLife Conceded The Unfair Competition Claim .....	20
7.	The Court Denies Sanctions Against GNI.....	21
B.	ThermoLife’s Files A Rule 59(e) Motion Requesting That The Court Consider Key Evidence Found On GNI’s Hard-Drives That GNI Hid From Dispositive Motion Briefing .....	22
C.	The District Court Declines To Consider The Evidence GNI Belatedly Produced, And ThermoLife Appeals.....	23
	SUMMARY OF THE ARGUMENT .....	23
	ARGUMENT .....	26
I	THE STANDARD OF REVIEW IS <i>DE NOVO</i> .....	26
II	THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT ON COUNTS I, II, IV, V, AND VI ON PRECLUSION AND LACK OF FALSITY GROUNDS .....	27
A.	The Lanham Act And Complementary FDCA Regulation.....	27
B.	The District Court Erred In Finding FDCA Preclusion .....	28

C.	The Court Also Reversibly Erred In Finding GNI's "Safe," "Legal" And "DSHEA-Compliant" Statements Were "Not False When Made" Because The FDA Had Not Yet Declared GNI's Products Unlawful And Unsafe .....	34
III	THE DISTRICT COURT REVERSIBLY ERRED IN GRANTING SUMMARY JUDGMENT ON LANHAM ACT COUNT III BECAUSE STATEMENTS THAT A PRODUCT IS "NATURAL" AND "NATURALLY OCCURRING" ARE MERE OPINIONS.....	38
IV	THE DISTRICT COURT ERRED IN FINDING NO ISSUE OF FACT ON MATERIALITY AND INJURY.....	40
A.	Since GNI's Products Would Have Been Banned Had GNI Truthfully Advertised Them As Harmful, Synthetic And Illegal Steroids, A Reasonable Trier Of Fact Easily Could Find That GNI's False Statements Were Material.....	41
B.	Since GNI Could Not Have Sold Illegal Steroids Without Lying About The Products' Attributes, A Reasonable Trier Of Fact Could Infer The Fact Of Damage.....	44
C.	At A Minimum, ThermoLife Should Have Been Allowed To Proceed On Its Claim For Disgorgement Of GNI's Profits As A Result of GNI's Willful Conduct .....	47
V	THE DISTRICT COURT ERRED IN BOTH FINDING THERMOLIFE DID NOT DEFEND THE STATE UNFAIR COMPETITION CLAIM AND IN FINDING THE CLAIM PREEMPTED.....	49
VI	THE DISTRICT COURT ABUSED ITS DISCRETION IN REFUSING TO REMEDY GNI'S DISCOVERY ABUSES .....	51
A.	Pertinent Factual Background .....	51
B.	The District Court Abused Its Discretion In Proceeding With The Summary Judgment Motion And Denying Rule 59 Relief .....	54
VII	THE DISTRICT COURT ERRED IN EXCLUDING ALL OF THERMOLIFE'S EXPERTS.....	57
A.	Governing Standards .....	58

B.	The Court Erred In Excluding Dr. Sox's Testimony That GNI's Products Were "Not Safe".....	59
C.	The Court Erred In Excluding Mr. Berger's Survey Evidence.....	61
D.	The Court Erred in Excluding the Market Testimony of Mr. Hornbuckle .....	62
E.	The Court Erred In Excluding Mr. Epperson's Damages Testimony.....	63
VIII	REVERSAL OF THE JUDGMENT TRIGGERS COSTS REVERSAL .....	65
IX	CONCLUSION .....	65
	STATEMENT OF RELATED CASES .....	67
	CERTIFICATE OF COMPLIANCE PURSUANT TO CIRCUIT RULE 32-1 .....	68
	CERTIFICATE OF SERVICE .....	69

## **TABLE OF AUTHORITIES**

	<b><u>Page</u></b>
<b>Cases</b>	
<i>Adams v. Watson</i> , 10 F.3d 915 (1st Cir. 1993) .....	44
<i>Anheuser-Busch, Inc. v. Natural Beverage Distrib.</i> , 69 F.3d 337 (9th Cir. 1995) .....	55
<i>Buckman Co. v. Plaintiff's Legal Comm.</i> , 531 U.S. 341, 121 S.Ct. 1012 (2001) .....	49-50
<i>Castrol, Inc. v. Quaker State Corp.</i> , 977 F.2d 57 (2d Cir. 1992) .....	36
<i>City of Pomona v. SQM N. Am. Corp.</i> , 750 F.3d 1036 (9th Cir. 2014) .....	59
<i>Clicks Billiards, Inc. v. Sixshooters, Inc.</i> , 251 F.3d 1252 (9th Cir. 2001) .....	61
<i>Collegenet, Inc. v. XAP Corp.</i> , 483 F. Supp. 2d 1058 (D. Or. 2007) .....	47
<i>Consumer Justice Ctr. v. Olympian Labs, Inc.</i> , 99 Cal. App. 4th 1056 (2002) .....	49
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 43 F.3d 1311 (9th Cir. 1995) .....	58
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 509 U.S. 579, 113 S.Ct. 2786 (1993) .....	58, 59
<i>Duarte v. Bardales</i> , 526 F.3d 563 (9th Cir. 2008) .....	56
<i>E. &amp; J. Gallo Winery v. Gallo Cattle Co.</i> , 967 F.2d 1280 (9th Cir. 1992) .....	61

<i>EFCO Corp. v. Symons Corporation</i> , 219 F.3d 734 (8th Cir. 2000).....	41
<i>Estate of Barabin v. AstenJohnson, Inc.</i> , 740 F.3d 457 (9th Cir. 2014).....	58
<i>Fortune Dynamic, Inc. v. Victoria's Secret Stores Brand</i> , 618 F.3d 1025 (9th Cir. 2010) .....	61
<i>Glover v. BIC Corp.</i> , 6 F.3d 1318 (9th Cir. 1992).....	54
<i>Hatch v. Reliance Ins. Co.</i> , 758 F.2d 409 (9th Cir. 1985).....	54
<i>Healthpoint, Ltd. v. Ethex Corp.</i> , 273 F. Supp. 2d 817 (W.D. Tex. 2001).....	33, 50
<i>Holk v. Snapple Beverage Corp.</i> , 575 F.3d 329 (3d Cir. 2009).....	39
<i>Intel Corp. v. Terabyte Int'l, Inc.</i> , 6 F.3d 614 (9th Cir. 1993).....	48
<i>Johnson &amp; Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.</i> , 299 F.3d 1242 (11th Cir. 2002) .....	41
<i>Kumho Tire Co., Ltd. v. Carmichael</i> , 526 U.S. 137, 119 S.Ct. 1167 (1999).....	58
<i>Lexmark Int'l v. Static Control Components, Inc.</i> , 572 U.S. ___, 134 S.Ct. 1377 (2014).....	47
<i>Lindy Pen Co. v. Bic Pen Corp.</i> , 982 F.2d 1400 (9th Cir. 1993) .....	47
<i>Lozano v. Montoya Alvarez</i> , ____ U.S. ___, 134 S.Ct. 1224 (2014) .....	56
<i>McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.</i> , 938 F.2d 1544 (2d Cir. 1991).....	36

<i>Messick v. Novartis Pharm. Corp.</i> , 747 F.3d 1193 (9th Cir. 2014) .....	58, 60
<i>Moss v. Walgreen Co.</i> , 765 F. Supp. 2d 1363 (S.D. Fla. 2011) .....	50
<i>Mutual Pharm. Co. v. Ivax Pharm., Inc.</i> , 459 F. Supp. 2d 925 (C.D. Cal. 2006) .....	33, 34
<i>N. Am. Watch Corp. v. Princess Ermine Jewels</i> , 786 F.2d 1447 (9th Cir. 1986) .....	56
<i>Nat'l Basketball Ass'n v. Motorola, Inc.</i> , 105 F.3d 841 (2d Cir. 1997).....	41
<i>Nat'l Products, Inc. v. Gamber-Johnson LLC</i> , 699 F. Supp. 2d 1232 (W.D. Wash. 2010).....	41
<i>Perez v. Nidek Co.</i> , 657 F. Supp. 2d 1156 (S.D. Cal. 2009).....	50
<i>Polo Fashions, Inc. v. Dick Bruhn, Inc.</i> , 793 F.2d 1132 (9th Cir. 1986) .....	48
<i>Pom Wonderful, LLC v. Coca-Cola, Co.</i> , 573 U.S. ___, 134 S.Ct. 2228 (2014).....	passim
<i>Primiano v. Cook</i> , 598 F.3d 558 (9th Cir. 2010).....	58, 59
<i>Procter &amp; Gamble Co. v. Chesebrough-Pond's, Inc.</i> , 747 F.2d 114 (2d Cir. 1984).....	36
<i>Prudential Ins. Co. v. Gibraltar Fin. Corp.</i> , 694 F.2d 1150 (9th Cir. 1982) .....	61
<i>Rikos v. Procter &amp; Gamble, Co.</i> , 782 F. Supp. 2d 522 (S.D. Ohio 2011) .....	50
<i>Sch. Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc.</i> , 5 F.3d 1255 (9th Cir. 1993).....	54

<i>Skydive Arizona, Inc. v. Quattrocchi,</i> 673 F.3d 1105 (9th Cir. 2012) .....	45, 48, 64
<i>Southland Sod Farms v. Stover Seed Co.,</i> 108 F.3d 1134 (9th Cir. 1997) .....	passim
<i>Stengel v. Medtronic,</i> 704 F.3d 1224 (9th Cir. 2012) .....	49
<i>TrafficSchool.com, Inc. v. Edriver Inc.,</i> 653 F.3d 820 (9th Cir. 2011).....	44, 47
<i>U-Haul Intern., Inc. v. Jartran, Inc.,</i> 793 F.2d 1034 (9th Cir. 1986) .....	41
<i>United States v. Hankey,</i> 203 F.3d 1160 (9th Cir. 2000) .....	62
<i>United States v. Sandoval-Mendoza,</i> 472 F.3d 645 (9th Cir. 2006).....	59
<i>Wallis v. Princess Cruises, Inc.,</i> 306 F.3d 827 (9th Cir. 2002).....	26
<i>Wyeth v. Levine,</i> 555 U.S. 555, 129 S. Ct. 1187 (2009).....	50

### **Statutes**

15 U.S.C. § 1117(a) .....	63
15 U.S.C. § 1121 .....	5
15 U.S.C. § 1125(a)(1).....	27
15 U.S.C. § 1127 .....	27
21 U.S.C. § 350b.....	8, 37
21 U.S.C. § 321(f).....	27
21 U.S.C. § 331 .....	27
21 U.S.C. § 337.....	27

21 U.S.C. § 342-1(a) .....	28
21 U.S.C. 343(a) .....	27
28 U.S.C. § 1291 .....	5
28 U.S.C. § 1331 .....	5
28 U.S.C. § 1338 .....	5
28 U.S.C. § 1367 .....	5

### **Rules**

Fed. R. App. P. 4 .....	5
Fed. R. App. P. 26.1 .....	i
Fed. R. Civ. P. 37 .....	54
Fed. R. Evid. 702 .....	59, 60
Ninth Circuit Rule 28-2.6 .....	67

### **Regulations**

21 C.F.R. § 102.33(d) .....	29
-----------------------------	----

### **Other Authorities**

<b>5 McCARTHY ON TRADEMARKS AND UNFAIR COMPETITION</b>	
§§ 27:31, 27:35 (4th ed. 2012) .....	41, 44
Designer Anabolic Steroid Act, S. 2012, 113TH Cong. (2014) .....	54

## **INTRODUCTION**

Appellant ThermoLife International, LLC (“ThermoLife”) appeals entry of summary judgment below on its Lanham Act false advertising claims and its Arizona common law claim for unfair competition.

ThermoLife and appellee Gaspari Nutrition, Inc. (“GNI”) compete to sell testosterone-boosting products to the public. From 2005 to 2010, GNI sold synthetic steroid-based testosterone-boosting products that it falsely advertised as “safe,” “natural” and “legal.” During that same timeframe, ThermoLife sold testosterone-boosting products that actually were safe, natural and legal. In 2010, the U.S. Food and Drug Administration (“FDA”) learned that GNI’s products contained steroidial unapproved new drugs and declared them unlawful and unsafe, and forced GNI to recall the products. ThermoLife sued GNI to redress its competitive injury during the 2005–2010 period when GNI obtained substantial sales at ThermoLife’s expense by virtue of its false advertising.

The district court ruled that because the federal Food, Drug and Cosmetics Act (“FDCA”) permits the FDA to regulate GNI’s products, the FDCA precludes ThermoLife’s Lanham Act claims that are premised on GNI’s advertisements occurring prior to the FDA actions in 2010. This was reversible error; in fact, the

U.S. Supreme Court settled this point in a recent decision, issued after the summary judgment below. *Pom Wonderful, LLC v. Coca-Cola Co.*, 573 U.S. \_\_\_, 134 S.Ct. 2228 (2014). In *Pom Wonderful*, the Supreme Court held that because the FDCA reflects no intent to displace the Lanham Act, the FDA's regulation of the labeling of ingested substances does not preclude a Lanham Act claim that seeks to recover for competitive injury. As stated in *Pom Wonderful*, “[q]uite to the contrary, the FDCA and the Lanham Act complement each other in the federal regulation of misleading food and beverage labels.” 134 S.Ct. at 2233.

The district court’s order cannot survive *Pom Wonderful*. Even prior to the Supreme Court’s decision in *Pom Wonderful*, the district court’s preclusion ruling was inexplicably overbroad. Essentially, the court ruled the FDCA immunized GNI’s false statements from 2005 to 2010 regarding the safety and legality of its products merely because GNI uttered those lies before the FDA declared the products illegal and unsafe in 2010. But there is no conflict between Lanham Act liability for GNI’s false statements and the FDA’s later actions.

The court also erred in ruling that ThermoLife did not raise a triable issue on the falsity, materiality and injury elements of its Lanham Act claims. Each element raises an issue of fact. GNI sold millions of dollars’ worth of unlawful and harmful

synthetic steroidal products by falsely advertising them as “safe,” “natural” and “legal.” But, as its 2010 product recall showed, if GNI had acted honestly, it could not have sold the products *at all*. From this fact alone, a reasonable trier of fact could easily infer falsity, materiality and injury. ThermoLife went further, adding reams of unnecessary but additional proof of these elements via message board posts from consumers, testimony of industry insiders and expert analyses. Instead of applying the summary judgment rule of reviewing only for legal sufficiency, the district court instead gave short shrift to ThermoLife’s evidence. In this Court’s *de novo* review, it should find a triable issue on each of ThermoLife’s claims based on the evidence.

The district court made other reversible errors. While the summary judgment briefing was underway, it came to light that GNI had withheld and hid evidence

Redacted . But motivated by massive profits, GNI willfully continued to advertise them falsely. Despite finding the withheld evidence relevant, the district court held GNI’s spoliation and discovery violations did not warrant sanctions. After summary judgment was entered, ThermoLife filed a Rule 59(e) motion, asking the court to revisit the issue in light of additional evidence GNI had produced after the briefing was complete. The court denied relief. This too was an abuse of discretion. The district court should not have

deprived ThermoLife of the opportunity to develop all the evidence at trial. Thus, independent of whether the record raised a triable issue, the Court should reverse to allow ThermoLife to further develop that record.

For reasons that ThermoLife cannot fathom, the district court gave little thought to the correct analysis on each of the legal issues presented. On FDCA preclusion, the court adopted the dumbfounding view that false advertising that occurs before FDA action is immune to later claims under federal statutes adopted specifically to allow a competitor to privately police false advertising. On falsity, the court took the equally dumbfounding view that a blatant lie is not a lie at all until a federal regulator declares it so. And even then, the previous lie was not “false when made” because the regulator had not yet made a ruling. The court applied similarly perplexing reasoning on materiality and injury, excluded *all* of both parties’ experts, and disregarded a willful wrongdoer’s attempt to hide damaging evidence in discovery.

Fortunately, this Court reviews summary judgment *de novo*. This Court should reverse with directions to allow ThermoLife to fully develop the record on GNI’s false advertising of its synthetic harmful steroid products as “safe,” “natural” and “legal.”

## **JURISDICTIONAL STATEMENT**

The District Court of Arizona had subject matter jurisdiction over ThermoLife's claims under 28 U.S.C. §§ 1331, 1338(a), (b) and 1367; 15 U.S.C. § 1121; and 28 U.S.C. § 1338(b). On January 10, 2014, the district court entered its order terminating the case and entered its final judgment. 1ER/5–44; 1ER/4. ThermoLife timely filed its notice of appeal of those two decisions on January 30, 2014. Fed. R. App. P. 4; 2ER/51–53. On March 11, 2014, the district court entered its order denying ThermoLife's motion to amend the final judgment. 1ER/2–3. On March 12, 2014, the district court entered its amended taxation judgment. 1ER/1. ThermoLife timely filed its amended notice of appeal to include an appeal of these two decisions on March 24, 2014. Fed. R. App. P. 4; 2ER/48–50.

This Court has jurisdiction under 28 U.S.C. § 1291 because the judgments and orders appealed are final decisions of the district court.

## **STATEMENT OF THE ISSUES**

1. Where federal law allows a seller to promote an ingested substance without advance FDA approval, and the FDA later declares the product unlawful and unsafe after the seller has marketed it for five years as “safe” and “legal,” does

the FDCA preclude Lanham Act and state law unfair competition claims that challenge the false advertising during the five years before the FDA intervened?

2. Where a seller advertises that its product are “natural” and contain “naturally occurring” ingredients, but the product includes synthetic steroidal compounds that are not found in nature, could a reasonable trier of fact find these statements were a “false or misleading description of fact,” rather than a mere “opinion”?

3. Does a Lanham Act plaintiff establish a triable issue on materiality and injury where there is evidence that (a) the defendant’s unlawful and harmful steroids could not legally have been sold at all during the five years before the defendant recalled them if it had not falsely advertised them, (b) consumers chose between the plaintiff’s and defendant’s products in the market; and (c) the plaintiff’s products embody the attributes the defendant falsely advertised were present in its products?

4. Did the district court abuse its discretion in granting summary judgment without considering highly damaging evidence that GNI had concealed through spoliation and discovery violations?

5. Did the district court abuse its discretion in excluding all of ThermoLife's expert opinions, given that Rule 702 and *Daubert* authorize only gatekeeping review, but the court below engaged in the type of factual weighing of the expert opinions that is reserved for the fact-finder at trial?

## **STATEMENT OF THE CASE**

### **I STATEMENT OF THE FACTS**

#### **A. 2005–2010: ThermoLife Sells Safe And Natural Supplements; GNI, Without The FDA’s Approval, Falsely Touts Its Steroidal Products As “Dietary Supplements” That Are “Natural,” “Safe,” “Supported by Rock-Solid Safety Data” And “Legal”**

ThermoLife is a dietary supplement company. It sold the supplements T-BOL, E-BOL, Tribosten and Ecdysten, all of which competed with the accused GNI products. *See* 3ER/345–46,490–91. ThermoLife’s supplements contained only natural, safe and legal ingredients and did not contain synthetic aromatase inhibitors or other illegal drugs. *See* 3ER/286–291,490–91.

Like ThermoLife, GNI is also a dietary supplement company. GNI sold testosterone boosters called Novedex XT, containing the aromatase inhibitor “ATD” (3,17-keto-etioli-triene), and Halodrol Liquigels and Halodrol MT, containing the aromatase inhibitors “5-alpha” (5-alpha-androstan-3,6,17-trione) and “6-oxo” (4-androstene-3,6,17-trione). 3ER/262-265,272,482¶13–16. ATD, 5-

alpha and 6-OXO are steroidal compounds not found in nature.<sup>1</sup> 3ER/265-66,272-74. GNI sold Novedex XT from January 2005 to October 2010, and sold the Halodrol products from July 2006 to April 2011. 3ER/482¶¶14–16.

Unlike the rules for prescription drugs, GNI did not need pre-market FDA approval of its products or its advertising. Rather, the Dietary Supplement Health and Education Act of 1994 (“DSHEA”) provides that a manufacturer must provide information to the FDA establishing the ingredient’s safety before bringing it to market only if the ingredient was not in the food supply prior to 1994. *See* 21 U.S.C. § 350b. GNI did not provide information to the FDA establishing the safety of its ATD, 5-alpha and 6-oxo steroidal compounds before placing Novedex XT, Halodrol Liquigels or Halodrol MT on the market. 3ER/271¶46.

#### **B. 2010: The FDA Finds GNI’s Products Contain Illegal And Unsafe Synthetic Steroids, Triggering Their Recall From The Market**

From 2005 to 2011, GNI sold synthetic steroidal products to consumers via promotions that touted the products as “natural,” “naturally occurring,” “legal,”

---

<sup>1</sup> Each of these compounds was identified as a designer steroid in a recent bill proposed by Senators Orrin Hatch and Sheldon Whitehouse, titled “The Designer Anabolic Steroid Control Act of 2014,” which would make punishable by up to 10 years in prison and a \$2.5 million fine the sale of each of the three compounds in GNI’s products at issue here. *See* Designer Anabolic Steroid Act, S. 2012, 113<sup>TH</sup> Cong. (2014).

“DSHEA-compliant,” “safe” and supported by “Rock-Solid Safety Data.” See 3ER/250–59 ¶¶1–4. In January 2010, a major dietary supplement retailer voluntarily recalled GNI’s Halodrol Liquigels, issuing a press release stating that the FDA informed the retailer that the FDA believed GNI’s product “contains ingredients that are steroids.” 3ER/266¶28. Eight months later, in September 2010, the FDA advised GNI that Novedex XT’s ATD ingredient “do[es] not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the [FDCA].” 3ER/262–63¶¶19–20. In response, GNI recalled Novedex XT pursuant to a press release that identified adverse effects associated with ATD, including “decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure and liver dysfunction.” 3ER/263–65¶¶22–24. At the same time, the FDA issued a formal enforcement report stating that Novedex XT and Halodrol Liquigels were “recalled because they are marketed as dietary supplements, but have been found to contain steroids or steroid-like substances, making them unapproved new drugs.” 3ER/266¶27.

**C. 2011–Present: ThermoLife Sues To Obtain A Remedy For GNI’s False Advertising And Presents Evidence That GNI’s Advertisements Were False, Were Material And Caused Injury**

On May 26, 2011, ThermoLife filed suit against GNI in the district court below. *See* Dkt. 1. On January 13, 2012, ThermoLife filed its First Amended Complaint, 2ER/141–97. ThermoLife’s first six Lanham Act counts challenged the following GNI false advertisements:

Count 1: GNI’s products were “legal”;

Count 2: Novedex XT complied with DSHEA;

Count 3: Novedex XT was “natural”;

Count 4: Novedex XT was “safe”;

Count 5: Halodrol Liquigels and Halodrol MT were DSHEA-compliant;

Count 6: Halodrol Liquigels and Halodrol MT were “safe.”

*Id.* at 164–83. ThermoLife’s Amended Complaint also asserted a claim for common-law unfair competition based on GNI’s false advertising statements. *Id.* at 190–93.<sup>2</sup>

---

<sup>2</sup> ThermoLife also brought three other Lanham Act counts (7–9), and a claim for tortious inference. To narrow the issues, ThermoLife does not challenge the summary judgment on those claims, and hence does not discuss them further.

On August 19, 2013, GNI moved for summary judgment on all of ThermoLife claims [*see* Dkt. 188] and also moved to exclude the reports and testimony of all of ThermoLife’s expert witnesses under *Daubert* [*see* Dkt. 178; Dkt. 181; Dkt. 201; Dkt. 202].

As discussed further in the argument section, while the case progressed from discovery to dispositive motion briefing, GNI spoliated relevant evidence and violated discovery rules. That conduct resulted in multiple sanctions motions filed both before and during summary judgment briefing. (*See* p. 51-54, *post*). In response, the district court merely allowed ThermoLife to file a single supplemental brief addressing the impact of GNI’s late-produced and concealed evidence on GNI’s summary judgment motion and *Daubert* motions. 1ER/45–46. At the deadline for the supplemental brief, GNI still had not produced tens of thousands of documents.

### **1. GNI’s Advertising Was False**

In opposition to summary judgment, ThermoLife showed all of the preceding facts. In addition, ThermoLife proffered testimony of Dr. Tim Ziegenfuss and Dr. Darren Willoughby, the doctors who had conducted the studies on which GNI relied to support its claims that its products were backed by “Rock-

Solid Safety Data.” 3ER/258–59¶4. Both doctors testified their studies were too small to be called “safety studies,” and their research was insufficient to support GNI’s advertising. 3ER/275–76¶¶63–67. Dietary supplement expert Dr. Thomas Sox also analyzed the Ziegenfuss and Willoughby studies and agreed they were insufficient to support GNI’s “safety” ads. 3ER/274–75¶¶ 59–62. He opined the participant size (a total of just 13 men between both studies) was inadequate to assess the possible side effects, the studies were not structured as “safety studies,” they did not appear to have been subjected to true peer review, and it was not clear whether Good Clinical Practices or Good Laboratory Practices were used to substantiate the data. *Id.*

Dr. Sox explained the industry standards and related testing procedures for assessing a dietary supplement’s safety. 2ER/117–27,136–38. After reviewing the scientific research, Dr. Sox concluded that neither Novedex XT nor the Halodrol products had been tested at the level needed to establish their safety. 2ER/117–27. He identified two peer-reviewed studies on aromatase inhibitors that “share the same mechanism of action” as those in Novedex XT and the Halodrol products, and he opined those studies create an assumption that those products are not safe. 2ER/125–27,138–40. Dr. Sox concluded, “Halodrol cannot be considered safe” and “Novedex XT was not safe.” 2ER/123,127.

Dr. Sox also testified that key ingredients in Novedex XT, Halodrol MT and Halodrol Liquigels are synthetic steroids that have never been present in the food supply. 3ER/265,272–74. He also reviewed GNI’s claim that ATD is natural because it is supposedly found in the bile of bovine intestines and a scientific paper that discussed how the steroid can be synthesized in a laboratory, Owen, R.W., Hill, M.J., & Bilton, R.F., *Biotransformation of chenodeoxycholic acid by Pseudomonas species NCIB 10590 under Anaerobic Conditions* (“Owen”). 3ER/272–73¶53–54. Dr. Sox opined *Owen* shows that ATD can only be synthesized in “unique laboratory conditions” using cow bile as one of several starting materials. 3ER/312–13. He explained that the anaerobic conditions under which *Owen* generated ATD “would not occur under more normal metabolic conditions” because a cow’s small intestine is an aerobic environment. *Id.* Thus, *Owen* does not support GNI’s claim and “this compound definitely cannot be considered natural.” *Id.* at 313.

## **2. GNI’s Advertising Statements Were Material**

In addition to the above evidence of materiality, ThermoLife presented a survey expert, James Berger, who surveyed GNI customers and concluded 98% of respondents cared whether a product is “legal,” 97% cared whether it was “safe,” and 95% cared whether it was “natural.” 2ER/101-111; 3ER/267–68¶32–34.

GNI's expert, Kenneth Hollander, similarly concluded that "natural" and "safe" are two of the top four factors considered by dietary supplement consumers. 3ER/268¶  
35,364–368.

ThermoLife also presented over 100 message board posts by customers on a popular bodybuilding website that questioned the safety and legality of GNI's accused products [*see* 3ER/268¶36], and that showed consumers often chose between ThermoLife's and GNI's testosterone boosters [*see* 3ER/270–71¶45]. For example, in one post, a message board commentator asked

Redacted

. These statements were false when made.

### **3. GNI's False Advertising Harmed ThermoLife**

Redacted

. But-

for GNI's false advertising, GNI could not sell these products at all, and its sales of the accused products before it recalled them thus would have gone to other sellers in this market, including ThermoLife.

Although no more was necessary to establish the fact of harm, ThermoLife introduced additional evidence in the form of its survey expert, Mr. Berger, its market expert, Ryan Hornbuckle, and its damages expert Ron Epperson. It also presented testimony from its President, Ron Kramer, from GNI's employees, and from a buyer for leading dietary supplement retailer, Europa Sports Nutrition.

Although the market for testosterone boosters is competitive, Mr. Hornbuckle testified GNI's false advertising disproportionately harmed ThermoLife because ThermoLife was one of the few companies that sold products that were safe, legal, DSHEA-compliant and natural. 3ER/278¶73. Mr. Epperson

opined that as a direct result of GNI's false advertising, ThermoLife's goodwill was harmed and it potentially lost profits in excess of six million dollars. 3ER/502–05. David Hayes, a buyer for Europa Sports Nutrition, testified ThermoLife's products were well-formulated and, despite the competition among testosterone boosters, he can only recall three companies that sold testosterone boosters in the relevant time period: GNI, ThermoLife and one other company.

3ER/269–70¶39,40.

Redacted

## **II PROCEEDINGS AND DISPOSITION BELOW**

### **A. After Hearing The Summary Judgment, *Daubert* And Sanctions Motions, The District Court Excludes Every Expert, Grants Summary Judgment, And Declines To Sanction GNI**

On January 8, 2014, the district court heard arguments on the motions for summary judgment, under *Daubert*, and for discovery sanctions. 2ER/54–97. It did not hold an evidentiary hearing on the *Daubert* motions.

Two days later, the district court issued a 40-page order granting summary

judgment on ThermoLife's claims as well as on GNI's counterclaims.<sup>3</sup> 1ER/5–44.

The order also granted all six of the parties' *Daubert* motions and denied both of ThermoLife's motions for sanctions. *Id.* That day, the court entered its final judgment. 1ER/4. With regard to the summary judgment against ThermoLife, the court's ruling was as follows:

**1. The Court Finds Preemption And Lack Of Falsity For Counts I-II & V (Advertising GNI Products as Legal or DSHEA-Compliant)**

The district court found the FDCA "preempted"<sup>4</sup> Counts I, II and V and any state law claim related to these statements. 1ER/29,35. Although the FDA found GNI's products were illegal in 2010 [3ER/262,264,266], the court ruled it would "usurp or undermine FDA authority" to allow Lanham Act claims based on GNI's false statements from 2005–2010 that its products were "legal" or "DSHEA-compliant" [1ER/29].

---

<sup>3</sup> ThermoLife cross-moved for summary judgment on GNI's counterclaims and the district court granted that motion. Because GNI did not appeal that ruling, ThermoLife does not discuss the counterclaims further.

<sup>4</sup> As the Supreme Court held, "Although the Court's pre-emption precedent does not govern preclusion analysis in this case, its principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *Pom Wonderful LLC*, 134 S. Ct. at 2236.

The court also ruled that Counts I, II and V failed as a matter of law “[b]ecause a dietary supplement or ingredient is not determined to be . . . not DSHEA-compliant, and/or illegal until the FDA proves and declares the product to be adulterated.” 1ER/30. As such, “GNI’s assertions to that effect were not false at the time they were made.” *Id.*

**2. After Excluding The Opinions Of A Safety Expert, The Court Also Finds Preemption Of Counts IV & VI (GNI Advertising Products As “Safe” and Supported By “Rock-Solid Safety Data”)**

The district court held Dr. Sox’s “report does not support his conclusion that Novedex XT ‘was not safe.’” 1ER/13. It added: “It would not be helpful to the jury to hear Dr. Sox’s opinion that GNI did not have sufficient research to prove that Novedex XT and the Halodrol products were ‘safe’ when the issue they would need to decide is whether, in fact, the products were ‘safe.’” 1ER/13.

After excluding Dr. Sox’s opinions, the court held Counts IV and VI “preempted,” based on reasoning that mirrored its rulings on Count I, II, and V. 1ER/29–30. It also held these claims failed “[b]ecause a dietary supplement or ingredient is not determined to be unsafe . . . until the FDA proves and declares the product to be adulterated.” 1ER/30. According to the court, GNI’s pre-2010 statements to consumers that its steroidal products were “safe” “were not false at

the time they were made” because the FDA had not yet spoken and did not declare the products unsafe until 2010. *Id.*

**3. On Count III, The Court Finds GNI’s False Advertising Of Its Products As “Natural” And “Naturally Occurring” To Be A Mere Opinion**

Although the district court did not find Count III preempted, it entered summary judgment on the ground that advertising a product as “natural” is a statement of opinion that is incapable of being proven false. 1ER/30–31. In the court’s words, “Without a standard for determining ‘natural’ or ‘naturally occurring,’ and no determination by the FDA at the time GNI’s statements were made, these statements represent opinions, not ‘a claim as to the absolute characteristics of a product.’” 1ER/31.

**4. The Court Rules No Reasonable Trier Of Fact Could Find Materiality**

The district court excluded Mr. Berger’s survey, report and testimony. 1ER/10–11. Without discussing the additional evidence of materiality, the court stated that “even if Mr. Berger’s opinions are considered, [ThermoLife] has not produced evidence sufficient to show a genuine issue of material fact regarding whether any of GNI’s allegedly false statements ‘actually deceived or has the

tendency to deceive a substantial segment of its audience' and 'the deception is material, in that it is likely to influence the purchasing decision.'" 1ER/31–32.

### **5. The Court Finds No Triable Issue On Injury**

On this element, the district court excluded ThermoLife's market expert, Mr. Hornbuckle, and damages expert, Mr. Epperson. 1ER/17,19. The court also stated:

[C]onsumers were given the choice among numerous products, not just two. [ThermoLife] has not shown that consumers would have chosen [ThermoLife's] products instead of GNI's products, but for GNI's allegedly false further advertising. . . . Moreover, as concluded above, GNI's statements have not been shown to have been false at the time they were made.

1ER/32.

### **6. The Court Erroneously Rules ThermoLife Conceded The Unfair Competition Claim**

In its summary judgment opposition papers, ThermoLife: (i) identified why its unfair competition claim did not seek to privately enforce DSHEA [*see* Dkt. 300, at 5–6]; (ii) presented further evidence and explanation of GNI's pattern of false advertising and recalling products to avoid FDA action [*id.* at 1–2, 6–8, 10–12, 14, 17 and n. 19, 20]; and (iii) defended the timeliness of its claims [*id.* at 14–16].

The district court nonetheless entered summary judgment on the unfair competition claim on the ground that, “[ThermoLife] did not defend its Count 10 for common law unfair competition, which alleges that GNI falsely marketed its products as DSHEA-compliant.” 1ER/35. The court also held that “Count 10 fails on the merits because § 337 of the FDCA ‘limits the ability of a private plaintiff to pursue claims under state law theories where such claims collide with the exclusive enforcement power of the federal government.’” *Id.*

## **7. The Court Denies Sanctions Against GNI**

In denying ThermoLife’s sanctions motions, the district court noted that “some of the email exchanges cast suspicion on GNI” and “[s]ome of the documents GNI failed to initially produce were relevant to the subject matter of this action and not unduly burdensome to produce.” 1ER/42. But it found any “[p]rejudice to [ThermoLife] has been mitigated by supplemental briefing, and [ThermoLife] has not shown that production of the ‘smoking gun documents’ before depositions would have altered the outcome of this litigation.” *Id.*

**B. ThermoLife's Files A Rule 59(e) Motion Requesting That The Court Consider Key Evidence Found On GNI's Hard-Drives That GNI Hid From Dispositive Motion Briefing**

On January 24, 2014, ThermoLife filed a Rule 59(e) motion, requesting the district court amend its judgment to, *inter alia*: (1) consider documents received by ThermoLife from six imaged GNI hard-drives after dispositive motion briefing was complete; and (2) stay the judgment pending the Supreme Court's *Pom Wonderful* decision. *See* Dkt. 419. In its motion, ThermoLife showed GNI produced over 25,000 documents from its imaged hard drives *after* ThermoLife's deadline to file a supplemental brief on the dispositive motions. *Id.* at 2–6. ThermoLife requested that the court reopen the record to consider the late-produced evidence, including

Redacted

ThermoLife argued that these documents should have been

available to its experts (or different experts) and to oppose summary judgment. *Id.* at 1, 10–11; Dkt. 443, at 6–7.

### **C. The District Court Declines To Consider The Evidence GNI Belatedly Produced, And ThermoLife Appeals**

On January 30, 2014, ThermoLife filed this appeal of the January 10, 2014 order and the accompanying judgment. 2ER/51–53.

On March 11, 2014, the district court denied ThermoLife’s Rule 59 motion. 1ER/2–3. On March 24, 2014, ThermoLife filed an amended notice of appeal, to include an appeal of the ruling on the Rule 59(e) motion and taxation judgment. 2ER/48–50.

### **SUMMARY OF THE ARGUMENT**

From 2005–2010, GNI made tens of millions of dollars selling anabolic steroids to unknowing athletes, fitness enthusiasts and other health-conscious individuals based on advertisements that falsely claimed its harmful steroid-based products were “supported by Rock-Solid Safety Data,” “Safe,” “Natural,” “Legal” and “DSHEA-compliant.” At the same time, ThermoLife sold its genuinely safe, natural and legal products in the same stores and on the same websites as GNI’s

falsely advertised products. In 2010, the FDA declared GNI's products unlawful and unsafe, and GNI recalled them. Yet the district court found that ThermoLife could not sue GNI to recover for the competitive harm and GNI's unjust enrichment during the five-year period of GNI's false advertising.

But weeks ago, the Supreme Court in *Pom Wonderful* rejected the district court's novel view of FDCA preclusion. The Supreme Court instead held such claims complement the oversight of the FDA, which does not have the resources to police the labeling of all dietary products in advance.

When the FDA forced GNI to recall these products, it mitigated future harm to the public and competitors. But the FDA did not compensate ThermoLife for lost sales when consumers believed GNI's lies and chose Novedex XT and the Halodrol products over ThermoLife's legal, natural and safe products. Nor did the FDA ensure GNI did not profit by forcing GNI to disgorge its ill-gotten sales. This is the purpose of the Lanham Act.

Moreover, the same evidence that supported ThermoLife's Lanham Act claims supported its state-law unfair competition claim. There is no precedent that supports the district court's decision that these claims are preempted.

The court's other rulings constituted impermissible fact-finding on summary judgment. If GNI had truthfully advertised its products as containing harmful synthetic steroids, it could not have sold those products *at all*. That alone establishes a triable issue on materiality, which is ordinarily an issue of fact for the jury. A reasonable fact-finder could also find materiality based on the nature of the products and false statements and the other evidence addressed below.

Further, the evidence raised a triable issue on injury. GNI's substantial sales of illegal products from 2005 to 2010 would have been distributed to the rest of the market. Thus, a reasonable trier of fact could easily infer that *at least one* of GNI's 2005–2010 sales would have gone to ThermoLife. Indeed, because ThermoLife and GNI competed for the same customers and ThermoLife's products embodied the attributes GNI advertised its products as possessing, it would be remarkable to infer that, as a matter of law, *none* of GNI's sales would have gone to ThermoLife and that ThermoLife suffered *zero* impact to its goodwill. Thus, with the fact of damage inferable, it was up to the jury—not the judge on summary judgment—to determine the amount of ThermoLife's damages.

The district court also failed to remedy GNI's spoliation and discovery violations. GNI did not produce its most relevant documents until after discovery

closed—and only after ThermoLife obtained an order compelling production of GNI's electronically stored information. Evidence produced by GNI only after the close of discovery showed

Redacted

ThermoLife was unable to rely on this evidence at the depositions of GNI's officers or use it with ThermoLife's own experts. Thus, independent of the court's error in finding the record at close of discovery failed to raise a triable issue, ThermoLife is entitled to a remand to reopen discovery and further develop the record.

Finally, on remand, ThermoLife should be allowed to rely on the experts that the district court erroneously excluded under *Daubert*. Much like its improper fact-finding on summary judgment, the court did not limit itself to the gate-keeping review that *Daubert* prescribes and instead engaged in the type of improper weighing of expert opinion that is reserved for the fact-finder at trial.

## ARGUMENT

### **I THE STANDARD OF REVIEW IS *DE NOVO***

The district court's summary judgment is reviewed *de novo*. See *Wallis v. Princess Cruises, Inc.*, 306 F.3d 827, 832 (9th Cir. 2002).

## **II THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT ON COUNTS I, II, IV, V, AND VI ON PRECLUSION AND LACK OF FALSITY GROUNDS**

### **A. The Lanham Act And Complementary FDCA Regulation**

Congress has specified the Lanham Act's intent is, *inter alia*, "to protect persons engaged in such commerce from unfair competition [and] to prevent fraud and deception in such commerce. . . ." 15 U.S.C. § 1127. The Act imposes civil liability on any person who "uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services, or commercial activities." *Id.* at § 1125(a)(1).

"Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers." *Pom Wonderful*, 134 S.Ct. at 2234.

In contrast, the FDCA "is designed primarily to protect the health and safety of the public at large." *Id.* It "prohibits the misbranding of food and drink," [*id.*] e.g., if an ingested substance's "labeling is false or misleading." *Id.* (citing 21 U.S.C. §§ 321(f), 331, 343(a)). The FDCA and its regulations preclude private

parties from suing under that statute and contains a provision pre-empting certain state laws on misbranding. *Id.* at 2235 (citing §§ 337, 342-1(a)).

## B. The District Court Erred In Finding FDCA Preclusion

The district court ruled the FDCA precluded Lanham Act claims directed at GNI's statements that its products were "legal," "DSHEA-compliant" and "safe." 1ER/29. A unanimous Supreme Court held otherwise in *Pom Wonderful*.<sup>5</sup>

In that case, a seller of pomegranate-blueberry juice, POM, sued Coca-Cola, the seller of a competing juice blend containing 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice and 0.1% raspberry juice. 134 S.Ct. at 2233. "Despite the minuscule amount of pomegranate and blueberry juices in the blend, the front label of the Coca-Cola product displays the words 'pomegranate blueberry' in all capital letters, on two separate lines." *Id.* at 2235. The FDA's regulations state that if a juice label does not name all the juices it contains and mentions only juices that are not predominant in the blend, then it must either declare the percentage content of the named juice or indicate that the named juice

---

<sup>5</sup> Justice Breyer took no part in the decision, but all eight other Justices joined the opinion that Justice Kennedy authored for the Court.

is present as a flavor or flavoring. *Id.* at 2234–35 (citing 21 C.F.R. § 102.33(d)).

The FDA does not preapprove juice labels under these regulations. *Id.* at 2235.

POM alleged Coca-Cola’s advertising misled consumers into believing the juice consisted predominantly of pomegranate and blueberry juice, drawing pomegranate juice sales away from POM. *Id.* The district court found the FDCA precluded the claim because the FDA had “directly spoken on the issues” via its juice blend regulation, but had not banned Coca-Cola’s labels. *Id.* at 2236. This Court affirmed. *Id.* The Supreme Court reversed. *Id.* at 2241–42.

The Supreme Court noted “neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA.” *Id.* at 2237. “In consequence, food and beverage labels regulated by the FDCA are not, under the terms of either statute, off limits to Lanham Act claims.” *Id.*

The Court added, the “Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose. Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and

safety.” *Id.* at 2238. Thus, Lanham Act suits help police conduct the FDA is unable to fully address. As the Court explained:

The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By ‘serving a distinct compensatory function that may motivate injured persons to come forward,’ Lanham Act suits, to the extent they touch on the same matter as the FDCA, ‘provide incentives’ for manufacturers to behave well. Allowing Lanham Act suits takes advantages of synergies among multiple methods of regulation.

*Id.* at 2238–39.

The Court also noted that precluding Lanham Act suits would produce a hole in the oversight of products that the FDA only partially regulates:

Unlike other types of labels regulated by the FDA, such as drug labels, it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters and other measures. Because the FDA acknowledges that it does not necessarily pursue enforcement measures regarding all objectionable labels, *ibid.*, if Lanham Act claims were to be precluded then commercial interests—and indirectly the public at large—could be left with less effective protection in the food and beverage labeling realm than in many other, less regulated

industries. It is unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels than in competitive markets for other products.

*Id.* at 2239 (internal citations omitted).

The Court thus held:

Congress did not intend the FDCA to preclude Lanham Act suits like POM's. The position that Coca-Cola takes in this Court that because food and beverage labeling is involved it has no Lanham Act liability here for practices that allegedly mislead and trick consumers, all to the injury of competitors, finds no support in precedent or the statutes.

*Id.* at 2241.

Here, GNI misled and tricked consumers, to the injury of its competitor ThermoLife. Accordingly, ThermoLife's Lanham Act claims are not precluded. Because it is doubtful whether *any* form of Lanham Act preclusion survives *Pom Wonderful*, the Court need go no further; the district court's ruling must be reversed.

Indeed, just as the Supreme Court suggested, ThermoLife's Lanham Act claims *complement* and *further* the FDA's actions with regard to GNI's products. The FDA contacted companies selling aromatase inhibitors, like GNI's Novedex XT and Halodrol products, as early as 2006, and conducted a surprise inspection of

GNI's facilities in December 2006 and again in September 2010. 3ER/271–72¶47.

On September 20, 2010, the FDA authored a formal press release regarding aromatase inhibitors that specifically listed GNI's Novedex XT as an offending product and stated, "The FDA concludes that products containing aromatase inhibitors have a reasonable probability of resulting in permanent impairment of body structure or function in at risk consumers." 3ER/262–63¶¶19–20. These FDA actions compelled GNI to recall the products at issue through a press release declaring the products unsafe. 3ER/263–64,266¶¶22–24,27. But in the interim, between 2005 and 2010, GNI continued to sell its products and compete with ThermoLife.

ThermoLife's Lanham Act claims further the FDA's ruling. The district court was twice wrong to rule "[p]lainly, judicial determination of the falsity of statements that certain dietary supplements are . . . 'safe' without a determination by the FDA would usurp or undermine FDA authority." 1ER/29. First, there *was* a "determination by the FDA" that GNI's products were unsafe—and it triggered a product recall. Second, even if the FDA had not acted, as the Supreme Court stated in *Pom Wonderful*, it furthers the FDA's authority to allow competitors to police false advertising of dietary products through Lanham Act claims. Thus, ThermoLife's Lanham Act claims based on GNI's "safe" and "Rock-Solid Safety

“Data” advertisements are not precluded, and, in fact, they further and complement the FDA’s actions.

So do the Lanham Act claims Counts in II, II and V based on GNI’s “legal” and “DSHEA-compliant” statements. Those statements risked misleading consumers into erroneously believing the FDA had approved GNI’s products. GNI was free to sell those products without claiming they were “legal” or “DSHEA-compliant.” Allowing Lanham Act liability based on the “legality” statements thus *further*s the FDA’s authority by refusing to treat the FDA’s mere silence as a license for a seller to falsely claim to the public that unlawful steroids are “legal.”

The district court’s ruling is baffling because even before the Supreme Court curtailed the preclusion doctrine in *Pom Wonderful*, preclusion was certainly not required here under even the Ninth Circuit view of preclusion as stated in *Pom Wonderful*. The FDCA does not preclude a false advertising claim over the similar phrase “FDA approved.” See *Mutual Pharm. Co. v. Ivax Pharm., Inc.*, 459 F.Supp.2d 925, 936 (C.D. Cal. 2006); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F.Supp.2d 817, 842 (W.D. Tex. 2001). It was generally understood that “once the FDA has taken a position on a particular matter, courts have consistently allowed the Lanham Act claim to proceed even if in determining the falsity of the alleged

representation the court must make reference to the FDA action.” *Mutual Pharm. Co.*, 459 F.Supp. 2d at 934–35. Because the FDA ultimately found that GNI’s products were not safe, were not legal and were not DSHEA-compliant, it would not undermine the FDA’s authority in the slightest to permit ThermoLife’s Lanham Act claims to proceed. This case was never preempted. The district court did not even need the Supreme Court’s guidance in *Pom Wonderful* to reach this obvious conclusion. In any event, *Pom Wonderful* settles the question and requires reversal.

**C. The Court Also Reversibly Erred In Finding GNI’s “Safe,” “Legal” And “DSHEA-Compliant” Statements Were “Not False When Made” Because The FDA Had Not Yet Declared GNI’s Products Unlawful And Unsafe**

For similar reasons, the district court also erred in ruling that GNI’s statements that its products were “safe,” “legal” and “DSHEA-compliant” were “not false at the time they were made” because the FDA did not finally determine the products were unsafe and illegal until 2010.

Because GNI’s products contained harmful steroids, they were unsafe from the first sale in 2005 until GNI’s 2010 recall, so GNI’s “safe” advertisements were false when made. A ruling from the FDA was never required to make these statements false; they were always false. As the FDA announced in its 2010 press release: “products containing aromatase inhibitors have a reasonable probability of

resulting in permanent impairment of a body structure or function in at risk consumers.” 3ER/263¶20. The FDA then compelled GNI to conduct a “Class 1 Recall.”<sup>6</sup> 3ER/263–64,271–72¶¶22–23,47–49; 3ER/434; 3ER/482¶18. In its recall press release, GNI listed serious health risks of aromatase inhibitors. 3ER/264¶24. ThermoLife’s expert also confirmed what the FDA found and GNI admitted: these products were not safe. 2ER/123,127.

Contrary to the district’s court’s odd logic, GNI’s false advertisements from 2005–2010 were not true merely because the FDA waited to act until 2010. And those advertisements did not become false in 2010 upon the FDA’s pronouncement. Serious health risks were always present in GNI’s products. Accordingly, it was false to advertise the products as “safe” at the time of each ad, and the FDA’s later finding that the products *were* always harmful does not and cannot make GNI’s earlier advertising true. To hold otherwise would convert the FDA’s delayed regulation into a shield for false advertising, raising the same concerns that animated the Supreme Court to reject unanimously the FDCA preclusion doctrine in *Pom Wonderful*. The district court’s “not false when made” view cannot be reconciled with *Pom Wonderful*, or with reality.

---

<sup>6</sup> A Class 1 Recall indicates a concern by the FDA that a serious health risk exists; sales and human consumption of the recalled product should cease immediately. 3ER/272¶49.

Also false when made were GNI's widely distributed advertisements that identified Novedex XT as supported by "Rock-Solid Safety Data." For advertising claims of testing support, "[i]f the plaintiff can show that the tests, even if reliable, do not establish the proposition asserted by the defendant, the plaintiff has obviously met its burden' of demonstrating literal falsity." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997) (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992)); see also *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991); *Procter & Gamble Co. v. Chesebrough-Pond's, Inc.*, 747 F.2d 114, 119 (2d Cir. 1984).

The only data GNI had available to it to support these statements were studies by Drs. Ziegenfuss and Willoughby. 3ER/258–59¶4. In their depositions, however, each doctor recited a list of tests they would need to conduct before their data could be used to support such a sweeping statement, and testified their studies did not include enough participants to be characterized as a "safety study." 3ER/275–76¶63–64. Both testified their research was insufficient to support GNI's specific advertising statements. 3ER/275–76¶63–64,67. Dr. Sox agreed, and described the far more robust data that the industry requires before it considers a claim of safety to be "rock-solid." 2ER/117–27,136–38. GNI has nothing of this kind and, thus, its advertising was demonstrably false.

The same is true of the “legal” and “DSHEA-compliant” statements. As Dr. Sox explained, a dietary supplement is only DSHEA-compliant or legal if its ingredients meet DSHEA’s requirements. 3ER/274, ¶57. Unless a dietary ingredient was present in the food supply prior to 1994, the ingredient must undergo the FDA’s “new dietary ingredient” screening before being sold. *See* 21 U.S.C. § 350b. ATD, 6-oxo and 5-alpha were not present in the food supply prior to 1994,

and Redacte  
d

. Thus, GNI’s statements that its products were “legal” or “DSHEA-compliant” were utterly false when made. Again, that the FDA did not declare the product illegal until 2010 is not a safe harbor, somehow making GNI’s false statements less false when made.

Moreover, to the extent the court suggested the statements were opinions rather than statements of fact because they referred to legality [1ER/30], this too was reversible error. GNI never offered an interpretation of DSHEA under which its products could ever conceivably be “legal” or “DSHEA-compliant.” Thus, this was not a matter of opinion—it was a fact. GNI made a false statement of fact when it advertised Novedex XT, Halodrol MT and Halodrol Liquigels as “legal” and “DHSEA-compliant.”

For all these reasons, ThermoLife raised a triable issue of fact on its Lanham Act Counts I, II, IV, V and VI which are premised on GNI's false "safe," "Rock-Solid Safety Data," "legal" and "DSHEA-Compliant" advertising statements.

### **III THE DISTRICT COURT REVERSIBLY ERRED IN GRANTING SUMMARY JUDGMENT ON LANHAM ACT COUNT III BECAUSE STATEMENTS THAT A PRODUCT IS "NATURAL" AND "NATURALLY OCCURRING" ARE MERE OPINIONS**

Although the district court did not find preemption of Lanham Act Count III, that GNI falsely declared its products "natural" [1ER/29–30], the court granted summary judgment on those claims because the statement "natural" was (in the court's view) mere opinion, and not "a claim as to the specific or absolute characteristics of a product." 1ER/31. This, too, was wrong.

While one might debate in the abstract whether a particular food ingredient qualifies as "natural," no such debate applies in this case. The synthetic steroids in GNI's product, ATD, 5-alpha and 6-oxo, are not found in nature. 3ER/272–74 ¶¶50–58. Apart from its arguments regarding the ability to synthesize ATD from cow bile under *unnatural* laboratory conditions, GNI never disputed this fact. 3ER/272,282 ¶¶53–55,93. Accordingly, there was ample evidence to permit a reasonable trier of fact to conclude GNI's products were not "natural" under *any* reasonable definition. That being so, GNI's assertions that its products were

“natural” or “naturally occurring” were not mere opinions—they were outright false statements of fact.

Neither the district court nor GNI cited any case law holding that the terms “natural” and “naturally occurring” are, as a matter of law, mere opinions. Quite the opposite: even in cases involving products whose “naturalness” was more debatable, those terms have been held actionable. *See Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340–41 (3d Cir. 2009).

In *Holk*, the FDA had considered whether it should adopt a policy defining when the term “natural” is appropriate to describe a beverage. The FDA stated “it believed ‘that if the term “natural” is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated.’” *Id.* at 341. “Nevertheless, the FDA declined to do so: ‘Because of resource limitations and other agency priorities . . . .’” *Id.* Although “the FDA declined to adopt a formal definition of the term ‘natural,’” [*id.* at 340], the Third Circuit did not declare the term “natural” was a non-actionable opinion or precluded by the FDA’s inaction. It instead remanded the case for further proceedings. *Id.* at 342.

Here, the district court’s view that ThermoLife’s claim failed as a matter of law due to lack of guidance from the FDA regarding what qualifies as “natural”

was wrong for two reasons. First, the FDA often does not define terms that sellers use in advertising. To disallow a Lanham Act claim merely because the FDA has not spoken would gut that law, and impermissibly so, for all the reasons articulated above and in *Pom Wonderful*. Second, no FDA guidance was needed because, however one might debate the “naturalness” of other substances, there was no debate here that GNI’s steroids were neither “natural” nor “naturally occurring” under any reasonable definition. At the very least, the issue was one of fact.<sup>7</sup>

#### **IV THE DISTRICT COURT ERRED IN FINDING NO ISSUE OF FACT ON MATERIALITY AND INJURY**

On both materiality and injury, the evidence easily sufficed to raise a triable issue of fact, and the district court reversibly erred in finding otherwise.

---

<sup>7</sup> ThermoLife’s expert described the type of case, unlike this one, where there might be a reasonable debate as to whether a product was “natural.” As he explained, those in the dietary supplement and food industries disagree on whether a product is properly labeled as “natural” when the product includes an ingredient that can be found in nature, but the material in the product is made synthetically (*i.e.*, when a product includes vitamin C that is synthetically made in a laboratory as opposed to harvested from natural materials like oranges or corn starch). That debate is irrelevant here because the steroids at issue are both made synthetically and appear nowhere in nature.

**A. Since GNI's Products Would Have Been Banned Had GNI Truthfully Advertised Them As Harmful, Synthetic And Illegal Steroids, A Reasonable Trier Of Fact Easily Could Find That GNI's False Statements Were Material**

The district's materiality analysis was baffling. When the FDA learned the truth about GNI's products, it triggered a product recall. 3ER/262-66¶19–20,22,24,27–28. GNI's false statements were the *only* reason it was able to sell those products before the recall [3ER/269,281–82¶¶38,90,94] and were thus unquestionably material. At the very least, a reasonable trier of fact could so find.

“When an advertisement is literally false (as opposed to implicitly deceptive), the plaintiff need not prove that any of its customers were actually persuaded by the advertising.” *EFCO Corp. v. Symons Corporation*, 219 F.3d 734, 740 (8th Cir. 2000).<sup>8</sup> A “plaintiff may establish this materiality requirement by proving ‘the defendants misrepresented an inherent quality or characteristic of the product.’” *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1250 (11th Cir. 2002) (quoting *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)); 5 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:35 (4th ed. 2012) (“One method of establishing materiality

---

<sup>8</sup> The Ninth Circuit adopted this rule in *U-Haul Intern., Inc. v. Jartran, Inc.*, 793 F.2d 1034, 1041 (9th Cir. 1986). See *Nat'l Products, Inc. v. Gamber-Johnson LLC*, 699 F. Supp. 2d 1232, 1237 (W.D. Wash. 2010).

involves showing that the false or misleading statement relates to an ‘inherent quality or characteristic’ of the product.””).

Here, an inherent quality of a dietary supplement is that it is safe and natural. This is also true of legality, since that term conveys the product does *not* contain unlawful steroids.

Citing this Court’s decision in *Southland Sod Farms*, the district court found that, even if it considered ThermoLife’s consumer survey, it failed to establish that GNI’s false statements, ““actually deceived or ha[d] the tendency to deceive a substantial segment of its audience and the deception is material, in that it is likely to influence the purchasing decision.’ See *Southland Sod Farms*, 108 F.3d at 1139.” 1ER/31–32.

But as this Court explained in *Southland Sod*, the evidence of materiality does not have to come from consumers. See 108 F.3d 1134, 1142–44 (9th Cir. 1997). Instead, where there is evidence the advertising had a *tendency* to mislead, a trial court errs in entering summary judgment. *Id.* In *Southland Sod*, the district court made the same mistake as the court below: it excluded the plaintiff’s survey evidence and entered summary judgment because the plaintiff supposedly could not prove the defendant’s advertising was material. See *id.* This Court reversed

both the summary judgment and the exclusion of expert testimony; if there is some evidence that consumers could be confused, this is an issue for the fact-finder. *See id.*

Here, the product recall alone showed consumers not only could be, but *were* confused—they bought products that the FDA and GNI later admitted should not have been sold at all. The nature of the products and the statements alone permitted an inference of materiality, since consumers of dietary supplements are inherently likely to be deceived by misrepresentations about the products' safety, legality or their purportedly natural origin.

Additional evidence was presented in the form of message board posts and consumer surveys. The posts showed that when GNI was advertising its products as "safe," "natural" and "legal," consumers were questioning whether these products in fact met GNI's claims—often while choosing between GNI's and ThermoLife's products. 3ER/268,270–71¶¶36,45. Approximately 90% of the survey respondents (which included both GNI and non-GNI customers) cared that a product was natural, safe, legal and DSHEA-compliant. 2ER/106–11; 3ER/266–68,¶¶31–34. GNI's own survey expert concluded "natural" and "safe" are two of the top four factors that supplement consumers consider in purchasing. 3ER/268¶35.

The totality of the materiality evidence was *overwhelming*—and thus easily sufficient to go to the jury.

**B. Since GNI Could Not Have Sold Illegal Steroids Without Lying About The Products' Attributes, A Reasonable Trier Of Fact Could Infer The Fact Of Damage**

“In a false advertising suit . . . [t]he plaintiff can prove his injury using ‘actual market experience and probable market behavior.’” *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 825 (9th Cir. 2011) (quoting *Adams v. Watson*, 10 F.3d 915, 923 (1st Cir. 1993)). It is hornbook law that “damage and standing will ordinarily be almost *automatic* if the parties are competitors and the advertising has a tendency to mislead some consumers, as demonstrated by evidence of either actual confusion or a consumer survey.” 5 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 27:31 (4th ed. 2012) (emphasis added).

Accordingly, this Court allows plaintiffs to “creat[e] a chain of inferences showing how defendant’s false advertising could harm plaintiff’s business.” *TrafficSchool.com*, 653 F.3d at 825. The Lanham Act “demands neither empirical quantification nor expert testimony to support a monetary award of actual damages; many sources can provide the requisite information upon which a

reasonable jury may calculate damages.” *Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d 1105, 1113 (9<sup>th</sup> Cir. 2012).

Here, the inference is simple because GNI could not have sold its products *at all* but-for its false advertising: GNI’s lies about its illegal steroids allowed it to enjoy sales it would not otherwise have made, and those sales would have gone to others in the market, including ThermoLife. *See* 3ER/269,277,281–82. That alone permits a reasonable jury to infer the fact of damage, which sufficed to send the case to trial. The amount of damages is an issue for trial. A reasonable trier of fact certainly was not compelled to find that *all* of GNI’s sales would have gone to others, and *none* to ThermoLife.

Not only could a reasonable fact-finder infer the fact of damage simply because GNI’s historical sales should have been fully redistributed, but ThermoLife presented ample other evidence that easily sufficed to send the case to trial. Such evidence included the testimony of its President, Ron Kramer, message board posts in which GNI representatives directly compared ThermoLife’s products to GNI’s illegal products, and expert testimony.

Mr. Kramer testified that GNI’s conduct negatively impacted ThermoLife’s goodwill and sales. 3ER/346. In addition, ThermoLife presented message board

posts from consumers explicitly deliberating between ThermoLife's and GNI's testosterone boosters. 3ER/270–71¶45. For example, in one post, message board commentators ask

Redacted

. ThermoLife also presented over 100 message board posts by customers on a popular bodybuilding website that questioned the safety and legality of GNI's accused products. 3ER/268¶36.

Based on this evidence, it was for the trier of fact to determine whether, but-for GNI's false advertising, ThermoLife would have captured *at least one* of GNI's ill-gotten sales. Even without the expert testimony addressed below, ThermoLife demonstrated a triable issue of fact on harm.

The district court did not address any of ThermoLife’s non-expert evidence, nor did it address the fact that none of GNI’s sales would have been possible but-for the false advertising. 1ER/32–33. This reflects a troubling pattern: the court repeatedly failed to heed—or even acknowledge—the governing summary judgment rule that it was reviewing only for legal sufficiency. The court’s finding on this issue was yet another reversible error.

**C. At A Minimum, ThermoLife Should Have Been Allowed To Proceed On Its Claim For Disgorgement Of GNI’s Profits As A Result of GNI’s Willful Conduct**

“Even when a plaintiff cannot quantify its losses with sufficient certainty to recover damages, it may still be entitled to . . . disgorgement of the defendant’s ill-gotten profits under § 1117(a).” *Lexmark Int’l v. Static Control Components, Inc.*, 572 U.S. \_\_, 134 S.Ct. 1377, 1392 (2014) (citing *TrafficSchool.com, Inc.*, 653 F.3d at 831). “When the plaintiff is unable to prove actual damages based on any measure . . . courts in the Ninth Circuit have generally allowed a monetary award based on equitable theories of unjust enrichment and deterrence. . . . To obtain such a recovery, the plaintiff must establish the defendant engaged in ‘willful misconduct.’” *Collegenet, Inc. v. XAP Corp.*, 483 F. Supp. 2d 1058, 1065 (D. Or. 2007) (citing *Lindy Pen Co. v. Bic Pen Corp.*, 982 F.2d 1400, 1405–07 (9th Cir. 1993)). This remedy exists because “[t]he purpose of § 35(a) is to ‘take all the

economic incentive out of [unfair competition].”” *Polo Fashions, Inc. v. Dick Bruhn, Inc.*, 793 F.2d 1132, 1135 (9th Cir. 1986).

As shown in the documents that GNI hid until after summary judgment briefing,

Redacted

Where a defendant’s conduct is willful, the standard for proving damages is lowered: “In reviewing a jury’s award of actual damages for intentional infringement, we accept ‘crude’ measures of damages based upon reasonable inferences so long as those inferences are neither ‘inexorable ... [nor] fanciful.’” *Skydive Arizona*, 673 F.3d at 1112 (quoting *Intel Corp. v. Terabyte Int’l, Inc.*, 6 F.3d 614, 621 (9th Cir. 1993)).

The district court failed to address the willfulness of GNI’s conduct. And as discussed below, it reversibly erred again in denying ThermoLife’s Rule 59 motion. This issue alone required a trial, and is yet another reversible error.

**V THE DISTRICT COURT ERRED IN BOTH FINDING THERMOLIFE DID NOT DEFEND THE STATE UNFAIR COMPETITION CLAIM AND IN FINDING THE CLAIM PREEMPTED**

The district court held ThermoLife did not defend its state law unfair competition claim and that the claim “fails on the merits” because it “collide[s] with the exclusive enforcement power of the federal government.” 1ER/35.

The court’s no-defense conclusion is simply wrong. See p. 34-41, *ante*; see also Dkt. 300, at 1–2, 5–8, 10–12, 14–17 and n. 19, 20.

So is its ruling that the claim would “collide” with federal enforcement. First, “there is no express preemption of cases involving the false advertising of dietary supplements in federal law under the Federal Trade Commission Act, the Federal Food, Drug, and Cosmetic Act, or the Dietary Supplement Health and Education Act (‘DSHEA’).” *Consumer Justice Ctr. v. Olympian Labs, Inc.*, 99 Cal. App. 4th 1056, 1063 (2002). As *Consumer Justice* explained, “It bears remarking at this point that Congress knows how to write a preemption clause if it wanted to.”

*Id.*

Furthermore, in *Stengel v. Medtronic*, 704 F.3d 1224 (9th Cir. 2012), this Court rejected a broad interpretation of *Buckman Co. v. Plaintiff's Legal Comm.*,

531 U.S. 341 (2001), that would impliedly preempt any state law claim that was premised, at least in part, on a federal violation. Rather, unfair competition claims may derive their “factual basis” from an FDA action, and may even “require reference to FDA definitions,” without constituting “an attempt to bring a private cause of action for a violation of the FDCA.” *See Moss v. Walgreen Co.*, 765 F.Supp. 2d 1363, 1366 (S.D. Fla. 2011). Numerous federal courts have recognized that common-law claims stemming from false advertising are not preempted. *See Perez v. Nidek Co.*, 657 F.Supp. 2d 1156, 1164–66 (S.D. Cal. 2009); *see also Rikos v. Procter & Gamble, Co.*, 782 F.Supp. 2d 522, 538 (S.D. Ohio 2011); *Healthpoint, Ltd.*, 273 F. Supp. 2d at 792–93.

These cases mirror the Supreme Court’s recent preemption jurisprudence. In *Wyeth v. Levine*, 555 U.S. 555, 577–78 (2009), the Court held statutes like the FDCA create a floor but not a ceiling for state law. As the Court explained, “[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA’s 70–year history.” *Id.*

Arizona common law provides a basis to hold liable any company that commits unfair competition in Arizona; it makes no difference whether the conduct

touches on the FDCA or DSHEA. ThermoLife's unfair competition claim is not preempted, and the district court erred in entering summary judgment on this claim.

## **VI THE DISTRICT COURT ABUSED ITS DISCRETION IN REFUSING TO REMEDY GNI'S DISCOVERY ABUSES**

ThermoLife presented evidence of GNI discovery abuses that warranted reopening discovery and denying summary judgment, or at the very least, reconsideration of the district court's exclusion of ThermoLife's experts. But the court abused its discretion in plowing ahead with summary judgment and then abused its discretion again in denying Rule 59(e) relief.

### **A. Pertinent Factual Background**

In July 2013, due to GNI's failure to produce relevant documents in discovery, the court-appointed discovery master ordered GNI to produce six of its computer hard drives for inspection. On August 19, 2013, before GNI produced any documents from the hard drives, the parties were required to file their motions Rule 56 and *Daubert* motions. 1ER/47.

On September 3, 2013, with motion briefing in full swing, ThermoLife moved for sanctions related to GNI's spoliation of certain evidence that could not

be recovered from the hard drive of GNI's CEO, Richard Gaspari. *See* Dkt. 216. ThermoLife's forensic expert, Ted Willard, noted that over the 14-month period in which Mr. Gaspari used this computer, Willard would expect to have seen deleted files "in the tens-of-thousands range" in the computer's Master File Table ("MFT") based on the computer's natural deletion of temporary files. 2ER/98–100. Instead, that file table reflected only "175 deleted files." *Id.* Willard opined that such an abnormally low deleted file count is typically the result of "some type of high-level process" that was "intentionally performed on the data," like the use of a file-wiping program. *Id.*

On November 21, 2013, two days after the completion of all dispositive and *Daubert*-motion briefing, ThermoLife finally began to receive the documents contained on the six GNI hard drives and discovered that many were highly relevant and responsive to its prior discovery requests; ThermoLife then moved for additional sanctions related to GNI's failure to produce those documents during discovery. *See* Dkt. 355. GNI's concealment prevented ThermoLife from providing those documents to its experts or utilizing them in the depositions of GNI employees who could not be subpoenaed for trial (or re-deposed for the then-pending dispositive motions). *Id.* at 10–11; *see* Dkt. 374, at 3–4.

On January 10, 2014, the district court denied the spoliation motion, finding the “evidence . . . too speculative for the Court to conclusively find willfulness, fault, or bad faith.” 1ER/41. It added, “the risk of prejudice to [ThermoLife] has been mitigated by [ThermoLife] obtaining the documents and emails it expected to find on Mr. Gaspari’s computer from other sources,” but did not identify the documents to which it was referring. *Id.* As for GNI’s failure to produce the documents from the hard drives, the court acknowledged that “some of the email exchanges cast suspicion on GNI” and “[s]ome of the documents GNI failed to initially produce were relevant to the subject matter of this action and not unduly burdensome to produce.” 1ER/42. But it held that any “[p]rejudice to ThermoLife has been mitigated by supplemental briefing, and [ThermoLife] has not shown that production of the ‘smoking gun documents’ before depositions would have altered the outcome of this litigation.” *Id.*

On January 24, 2014, ThermoLife filed a Rule 59(e) motion to amend the January 10, 2014 Order and Judgment. *See* Dkt. 419. It requested the court reconsider its exclusion of ThermoLife’s experts and reopen discovery in light of the over 25,000 documents ThermoLife received from the six imaged GNI hard drives after dispositive and *Daubert*-motion briefing was complete. *Id.* at 2–6.

Those documents show

Redacted

Redacted

On March 11, 2014, the district court

denied the motion, stating ThermoLife “largely seeks reconsideration.” 1ER/2–3.

**B. The District Court Abused Its Discretion In Proceeding With The Summary Judgment Motion And Denying Rule 59 Relief**

The district court’s denial of discovery sanctions and Rule 59(e) motions is reviewed for abuse of discretion. *See Hatch v. Reliance Ins. Co.*, 758 F.2d 409, 416 (9th Cir. 1985); *Sch. Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc.*, 5 F.3d 1255, 1262 (9th Cir. 1993).

Under Fed. R. Civ. P. 37, a district court has the discretion to impose sanctions in response to the spoliation of relevant evidence or incomplete or evasive responses to discovery requests. *See Glover v. BIC Corp.*, 6 F.3d 1318, 1329 (9th Cir. 1992).

Here, it was undisputed that: (1) GNI’s discovery violations caused the discovery master to order the inspection of hard drives that yielded the belated production of over 25,000 documents *after* completion of expert discovery and dispositive motion and *Daubert* briefing; and (2) GNI’s CEO’s computer contained an abnormally low number of deleted files consistent with the intentional wiping of the hard drive. The district court found this to be “inconclusive” evidence that GNI

had acted with “willfulness, fault, or bad faith.” 1ER/41. That finding—itself dubious in light of the lack of any credible explanation for the wiped clean hard-drive—could at most justify declining terminating sanctions. *See Anheuser-Busch, Inc. v. Natural Beverage Distrib.,* 69 F.3d 337, 347 (9th Cir. 1995) (sanction of dismissal requires a showing of “willfulness, fault, or bad faith”).

The court’s finding could not, however, justify failing to ensure ThermoLife was not prejudiced from GNI’s late production. Even if GNI was merely negligent in its concealment and spoliation, the innocent party, ThermoLife, should not suffer for GNI’s derelictions. Because ThermoLife indisputably had no opportunity to review the evidence that GNI had either spoliated or had produced only when ordered by the discovery master, the district court should not have excluded ThermoLife’s experts or entered summary judgment without giving ThermoLife the opportunity to fully explore the new evidence. And the supplemental briefing that the court allowed did not mitigate the prejudice to ThermoLife because that briefing occurred prior to GNI’s late production of the thousands of withheld documents. Dkt. 419, at 2–6.

It was therefore an abuse of discretion to proceed with the summary judgment motion and exclude all ThermoLife’s experts without affording

ThermoLife the opportunity to further develop the evidence with its experts. *See N. Am. Watch Corp. v. Princess Ermine Jewels*, 786 F.2d 1447, 1451 (9th Cir. 1986) (“Belated compliance with discovery orders does not preclude the imposition of sanctions. Last-minute tender of documents does not cure the prejudice to opponents nor does it restore to other litigants on a crowded docket the opportunity to use the courts.”).

It was an independently reversible abuse of discretion to decline to grant Rule 59 relief. “To prevail on a Rule 59(e) motion because of newly discovered evidence, the movant must show the evidence (1) existed at the time of the trial or proceeding at which the ruling now protested was entered; (2) could not have been discovered through due diligence; and (3) was of such magnitude that production of it earlier would have been likely to change the disposition of the case.” *Duarte v. Bardales*, 526 F.3d 563, 567 (9th Cir. 2008) (internal citations omitted), overruled on other grounds, *Lozano v. Montoya Alvarez*, 134 S.Ct. 1224 (2014).

Here, these criteria plainly were met. ThermoLife exercised due diligence but was unable to discover the evidence earlier because GNI did not produce responsive documents requested in discovery until after discovery and dispositive motion briefing was complete—and even then GNI did so only in response to a

court order. Moreover, the new evidence was likely to change the outcome here.

Redacted

Among other things, this evidence of willful misconduct alone raised a triable issue on whether a disgorgement remedy was appropriate. (*See* p. 47-48, *ante*.) Because the district court also erroneously found no triable issue on falsity, materiality and injury, the new evidence also further established a triable issue on those elements.

Accordingly, either based on the district court's abuse of discretion in proceeding with the summary judgment and *Daubert* motions or its ensuing independent abuse of discretion in denying Rule 59 relief, the Court should reverse with directions to permit ThermoLife to reopen discovery and further develop the factual record based on the late-produced evidence.

## **VII THE DISTRICT COURT ERRED IN EXCLUDING ALL OF THERMOLIFE'S EXPERTS**

Irrespective of the court's rulings on the admissibility of its experts' opinions, ThermoLife raised a triable issue of fact. Nevertheless, because those

experts offered admissible opinions that will help the trier of fact, the district court abused its discretion in excluding those experts.

### A. Governing Standards

The Court reviews rulings on the admissibility of expert testimony for abuse of discretion. *Primiano v. Cook*, 598 F.3d 558, 563 (9th Cir. 2010).

“Rule 702 should be applied with a ‘liberal thrust’ favoring admission . . . .” *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588, 113 S.Ct. 2786 (1993)). Rule 702 requires that “[e]xpert testimony . . . be both relevant and reliable . . . .” *Id.* (quoting *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014)). “The relevancy bar is low, demanding only that the evidence ‘logically advances a material aspect of the proposing party’s case.’” *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995)). “The reliability threshold requires that the expert’s testimony have ‘a reliable basis in the knowledge and experience of the relevant discipline.’” *Id.* at 1197 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149, 119 S.Ct. 1167 (1999)).

“While the district court must act as a gatekeeper to exclude ‘junk science’ under *Daubert*, Federal Rule of Evidence 702(a) includes within its scope all evidence that would ‘help the trier of fact ... to determine a fact in issue.’” *Id.* The judge is not a fact-finder, and it is the jury’s role to weigh the testimony. *Primiano*, 598 F.3d at 565 (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006)). The court “should not make credibility determinations that are reserved for the jury.” *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014). “Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564 (citing *Daubert*, 509 U.S. at 596).

Here, the district court did not heed Rule 702’s liberal thrust, and incorrectly arrogated to itself the task of weighing the experts’ opinions. As a result, the court excluded every single expert in the case. This was an abuse of discretion.

#### **B. The Court Erred In Excluding Dr. Sox’s Testimony That GNI’s Products Were “Not Safe”**

Dr. Sox, a 20-year veteran of the dietary supplements industry, examined the facts and scientific studies and reached two main conclusions: (1) Novedex XT and the Halodrol products could not be considered “safe”; and (2) GNI did not have a sufficient basis to call Novedex XT “safe.” 2ER/114–15,123 127–32. The district

court held “[i]t would not be helpful to the jury to hear Dr. Sox’s opinion that GNI did not have sufficient research to prove that Novedex XT and the Halodrol products were ‘safe,’ when the issue they would need to decide is whether, in fact, the products were ‘safe.’” 1ER/14.

However, Dr. Sox’s testimony has a reliable basis in the knowledge and experience of the relevant discipline. *See Messick*, 747 F.3d at 1196. That being so, the “relevancy bar is low,” so the court should have admitted his opinion. Indeed, one of the advertising statements at issue was GNI’s false claim that its harmful steroids were supported by “Rock-Solid Safety Data.” 3ER/258–59¶4. Thus, it was directly relevant for the jury to assess the quantum and quality of the “data” that supported GNI’s claim. Since those are topics that are beyond the ken for ordinary lay jurors, testimony from an expert who has knowledge and experience regarding what quantum and quality of data is considered “solid” in this industry plainly “help the trier of fact . . . to determine a fact in issue.” Fed. R. Civ. P. 702; *see Messick*, 747 F.3d at 1196. Dr. Sox was just such an expert. The district court abused its discretion in excluding this admissible expert evidence.

### C. The Court Erred In Excluding Mr. Berger's Survey Evidence

Mr. Berger provided survey evidence and concluded “an extremely high percentage of respondents that had previously taken one of [GNI]’s products at issue in this lawsuit indicated [that if] they were informed that [GNI]’s advertising was false they would stop using the product and seek out another product in the same product line with [the] advertised benefits.” 2ER/110. The district court, however, abused its discretion by excluding Mr. Berger’s testimony for technical reasons that speak to weight and not admissibility. 1ER/7–10.

“[S]urveys in trademark cases are to be admitted as long as they are conducted according to accepted principles” and “[t]echnical unreliability goes to the weight accorded a survey, not its admissibility.” *E. & J. Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280, 1292 (9th Cir. 1992) (quoting *Prudential Ins. Co. v. Gibraltar Fin. Corp.*, 694 F.2d 1150, 1156 (9th Cir. 1982)). Under this precedent, and this Court’s reversals of decisions excluding survey evidence,<sup>9</sup> the district court abused its discretion in excluding Mr. Berger’s survey evidence.

---

<sup>9</sup> See, e.g., *Fortune Dynamic, Inc. v. Victoria’s Secret Stores Brand*, 618 F.3d 1025 (9th Cir. 2010); *Southland Sod Farms*, 108 F.3d at 1143; *Clicks Billiards, Inc. v. Sixshooters, Inc.*, 251 F.3d 1252 (9th Cir. 2001).

**D. The Court Erred in Excluding the Market Testimony of Mr. Hornbuckle**

Mr. Hornbuckle spent many of his 20-years of experience in the supplement industry working directly with the narrow category of products implicated in this case. 3ER/485–86,492–93. He also has experience as a consultant evaluating products and product positioning. *Id.* He stated that, “[i]f not for the false advertising of unapproved dietary supplements by [GNI], [ThermoLife] would have undoubtedly performed better in the marketplace as a whole,” and estimated that ThermoLife would have captured 42.7% of GNI’s sales volume from 2005 to 2010. *Id.* at 490. Yet the district court excluded Mr. Hornbuckle’s testimony, questioning his qualifications and stating he “made up a methodology.” 1ER/15–17.

The Ninth Circuit has held the reliability of “non-scientific” expert testimony “depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it.” *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000). Mr. Hornbuckle has decades of knowledge and experience in the dietary-supplement industry, making his testimony sufficiently reliable. The asserted defects in his methodology are relevant to the weight to be given to the testimony, not to admissibility. See *Southland Sod Farms*, 108 F.3d at

1143. The district court abused its discretion in excluding Mr. Hornbuckle's testimony.

#### **E. The Court Erred In Excluding Mr. Epperson's Damages Testimony**

ThermoLife retained Mr. Epperson to quantify its damages. 3ER/496. Neither GNI nor the district court challenged Mr. Epperson's qualifications. *See* Dkt. 201; 1ER/17–19. Using universally accepted principles, Mr. Epperson calculated three categories of damages pursuant to 15 U.S.C. § 1117(a): 1) ThermoLife's actual damages in the form of lost profits, 2) ThermoLife's actual damages in the form of lost goodwill, and 3) GNI's profits from the sale of improperly advertised products. 3ER/498–509. For the first and third categories, Mr. Epperson started from a figure representing GNI's sales of the improperly advertised products. *Id.* at 502–03. GNI did not dispute this figure.

Yet the court broadly rejected his work, on the grounds that: (1) “he provide[d] no basis for his conclusion that all of GNI's profits were causally related to its false advertising and therefore must be disgorged”; and (2) he had “no basis for concluding that any specific percentage of [GNI's customers] would have purchased [ThermoLife's] testosterone boosting products.” 1ER/18–19. As demonstrated above, the court's grounds for exclusion are factual issues in dispute.

Furthermore, Mr. Epperson addressed these issues in his report, stating, “I have no opinions on the liability issues in this matter, and my opinions are directed to the damages issues outlined in this report. It is my understanding that the causation element mentioned above is a matter for the finder of fact.” 3ER/502.

As GNI acknowledged below, nothing in the Lanham Act required Mr. Epperson to causally link GNI’s profits to its false advertising. *See* Dkt. 201, at 7:22–23. Second, he provided a range of damages based on GNI’s profits and conclusions of ThermoLife’s other experts [3ER/509]; he never opined that a specific percentage of GNI’s customers would have purchased ThermoLife’s products, and the statute does not require him to do so. In fact, as noted above, the Lanham Act does not even require expert testimony to support a damages award. *See Skydive Arizona*, 673 F.3d at 1113.

At bottom, the court excluded Mr. Epperson because he calculated damages without definitively proving ThermoLife’s case. But that job is for the finder of fact. By surpassing its gatekeeping role and engaging in improper weighing of Mr. Epperson’s testimony, the district court abused its discretion in excluding his testimony.

## **VIII REVERSAL OF THE JUDGMENT TRIGGERS COSTS REVERSAL**

Because the costs award rests on prevailing party status, reversal of the judgment on any of the above grounds also requires reversal of the costs award.

## **IX CONCLUSION**

The district court was inexplicably hostile to claims based on GNI’s willful false advertising—advertising that enabled it to deceive consumers for years into spending tens of millions of dollars on unlawful and harmful synthetic steroids instead of ThermoLife’s safe, natural and legal products. The court also inexplicably turned a blind eye to GNI’s discovery abuses that attempted to hide the most damaging evidence. In this Court’s *de novo* review of the summary judgment, it should reverse the judgment as well as related costs award and the exclusion of ThermoLife’s experts. It should also remedy GNI’s discovery abuses with directions to the district court to allow ThermoLife to further develop the factual record on remand, prior to conducting a jury trial on all claims.

DATED: July 10, 2014

KERCSMAR & FELTUS PLLC

REED SMITH LLP

By /s/ Raymond A. Cardozo  
Raymond A. Cardozo

Attorneys for Plaintiff, Counter-Defendant  
and Appellant ThermoLife International,  
LLC

**STATEMENT OF RELATED CASES**

Pursuant to Ninth Circuit Rule 28-2.6, Appellant states that it is aware of no related cases pending in this Court.

DATED: July 10, 2014

KERCSMAR & FELTUS PLLC

REED SMITH LLP

By /s/ Raymond A. Cardozo  
Raymond A. Cardozo

Attorneys for Plaintiff, Counter-Defendant  
and Appellant ThermoLife International,  
LLC

**CERTIFICATE OF COMPLIANCE PURSUANT TO CIRCUIT RULE 32-1**

I certify that the foregoing brief is proportionately spaced, has a typeface of 14 points, and contains 13,570 words.

DATED: July 10, 2014

KERCSMAR & FELTUS PLLC

REED SMITH LLP

By /s/ Raymond A. Cardozo  
Raymond A. Cardozo

Attorneys for Plaintiff, Counter-Defendant  
and Appellant ThermoLife International,  
LLC

## CERTIFICATE OF SERVICE

I hereby certify that, on July 11, 2014, I electronically filed the foregoing Appellant's Opening Brief (Public Version [Containing Redactions of Confidential Passages]) with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the Appellate CM/ECF System.

I further certify that all of the participants in the case are registered CM/ECF users.

Dated: July 11, 2014

/s/ Raymond A. Cardozo  
Raymond A. Cardozo